

4.0 REFERENCE DATA

In vitro ER TA assays measure the ability of a test substance to initiate or block transcription of a reporter gene, or to induce cell proliferation or inhibit its induction by a reference estrogen, in an appropriate cell line. The ability of a test substance to activate or inhibit estrogen-induced transcriptional activation *in vitro* suggests, but does not demonstrate, the ability of the substance to act *in vivo* as an estrogen agonist or antagonist.

The purpose of this BRD is to assess the performance of various *in vitro* ER TA assays with regard to their sensitivity for detecting weak ER agonists and antagonists and their reliability within and among laboratories and across procedures. No attempt is made to evaluate their performance with respect to results obtained in *in vivo* endocrine disruptor assays (e.g., the rodent uterotrophic assay). Such comparisons will be addressed elsewhere. Therefore, no reference data are included for measuring the biological relevance of the *in vitro* ER TA assays.

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